

**Amendment and Response**

Applicant: David E. Francischelli et al.

Serial No.: 10/752,135

Filed: January 6, 2004

Docket No.: M190.257.101/P8922.06

Title: SYSTEM FOR ASSESSING TRANSMURALITY OF ABLATION LESIONS

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**REMARKS**

The following remarks are made in response to the Non-Final Office Action mailed July 18, 2007. Claims 1-29 were pending. Claims 1-12 and 16-29 were rejected. Claims 13-15 have been objected to. With this Response, claims 1, 13-15, 20 and 21 have been amended. Claims 1-29 are pending in the application and are presented for reconsideration and allowance.

**Specification**

The specification has been amended to correct the claim of priority and to include identification of the U.S. Patent the issued from the incorrectly identified patent application, as required in the Office Action. No new matter is included.

**Oath/Declaration**

The Office Action asserts that the declaration does not comply with 37 CFR 1.63 (a). Applicant asserts that the submitted declaration is in compliance with 37 CFR 1.63, as defined in 37 CFR 1.56. Specifically, the submitted declaration states that the inventors "acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)." This language (as used in applicant's declaration) was specified by the USPTO and was widely used prior to the 1992 amendment of 37 CFR 1.63(b).

The USPTO explicitly stated that the pre-1992 oaths comply with the now used language and would continue to be accepted by the Office. In its affirmation, the USPTO stated:

Reply: The averments in oath or declaration forms presently in use that comply with the previous § 1.63 or § 1.175 will also comply with the requirements of the new rules. Therefore, the Office will continue to accept the old oath or declaration forms as complying with the new rules." See, 57 FR 2034 (emphasis added).

Therefore, applicant respectfully requests withdrawal of the objection to the declaration.

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**Claim 20**

Applicants added independent claim 20 in the amendment of January 23, 2006. Claim 20 is amended in this response. Applicants respectfully request examination and allowance of claim 20.

**Claim Rejections under 35 U.S.C. § 102**

Claims 21, 22, 25 and 29 are rejected under 35 U.S.C. 120(b) as being anticipated by Stern et al. US Patent No. 5,443,463. Claim 21 is an independent claim, and claims 22, 25, and 29 depend from claim 21.

Claim 21 includes the amended features of “an output device in communication with the pad, the output device operatively adapted to indicate continuous transmuralty of the ablated tissue based on the sensed temperature.” Claim 21 also includes the amended features of “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.” Stern teaches a system for coagulating blood with heating electrode disposed on a first side of tissue and temperature sensors disposed on an opposite side of the tissue. The Office Action states at page 3 that “the Stern et al system is inherently adapted to provide an indication of transmuralty of the lesion (i.e. coagulation zone) since it is monitoring tissue temperature.” Applicants respectfully submit that the amended claim is not anticipated by Stern or made obvious in the prior art.

With regard to the claimed feature of “an output device,” the Office Action states at page 3 that “an output device (i.e. computer 114) is used to display parameters.” Applicants respectfully traverse this assertion. The computer 114 is not provided with or coupled to a device to “display” parameters. Instead, the computer 114 in Stern receives inputs from the temperature sensors 31 and provides an output to control the switch banks 134, 136, and the external RF control through interface 112. (Stern, column 5, lines 18-46, and figures 3A and 3B). There is nothing to indicate that the computer 114 is used to display parameters as set out in the Office Action. More importantly, there is nothing to teach or make obvious the claimed features of “an output device in communication with the pad, the output device operatively

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adapted to indicate transmurality of the ablated tissue based on the sensed temperature.”

Accordingly, these claimed features are not found or made obvious in Stern.

Further, amended claim 21 provides a non-obvious improvement over the device of Stern. The device of Stern uses temperature sensors to control the heating of tissues, which is used to perform coagulation of nearby blood vessels. Stern teaches the “temperature sensors 31 or 46 are employed to sense the tissue temperature. Allowing the tissue temperature to reach a desired value and maintaining that temperature at that level for an appropriate period of time provides the physician with feedback concerning the coagulation process.” (Stern, column 6, lines 16-20). Accordingly, the temperature sensors of Stern do not directly or inferentially measure coagulation. Rather, they provide a value that must be maintained at a predetermined level for a known period of time to effect coagulation.

The device of Stern includes several of the issues of other prior art techniques, including the inability to detect whether coagulation has occurred or whether it is continuous. The device of Stern takes point measurements of temperature to control heating of tissue. After an appropriate amount of time, the surgeon cuts the tissue with only a guess that continuous coagulation has occurred. Stern does not teach or make obvious the need to indicate continuous coagulation. It merely assumes through a series of physically spaced-apart temperature measurements that enough coagulation has occurred so that tissue will stop bleeding. In contrast, the claim 21 sets forth a system “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.”

Applicants have solved the problem inherent in devices such as Stern that point measurements and visual inspection of one side of tissue do not provide a clear indication of continuous ablation. Stern involves a coagulation device and these devices do not recognize that the lack of clear indication of continuity can be a great problem in ablation. Coagulation spreads relatively easily and a miscalculation with the device of Stern leads to only minor bleeding that can be readily repaired because the surgeon is still working in the area with the device in hand. On the other hand, continuous ablation can be more difficult to achieve than continuous coagulation. Further, a lack of continuous ablation can lead to severe problems including an ineffective treatment of arrhythmia or trauma. These effects cannot be readily repaired as with

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coagulation because they are often not detectable until after the surgery is completed.

Accordingly, the prior art need not provide a coagulation device of Stern with the measurements and indications of Applicants' ablation device.

This issue with devices such as Stern is solved in the present claims with the amended features of "wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue" and "the output device operatively adapted to indicate continuous transmuralility of the ablated tissue based on the sensed temperature." These features are not taught in Stern, and the problems solved by these features are not recognized in Stern, which also does not then suggest a solution.

Applicants respectfully submit that amended independent claim 21 is patentably distinguishable and allowable over Stern. Claims 22, 25, and 29, by virtue of their dependency, are patentably distinguishable and allowable over Stern also. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 21, 22, 25, and 29 under 35 U.S.C. 102(b) as being anticipated by Stern.

**Claim Rejections under 35 U.S.C. § 103****Claims 1-4, 6-9, 12, 16 and 19**

Claims 1-4, 6-9, 12, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. US Patent No. 5,443,463 in view of the teaching of Nagai et al. US Patent No. 5,172,949. Claim 1 is an independent claim, and claims 2-4, 6-9, 12, 16, and 19 depend from claim 1.

Claim 1 has been amended to include the amended features of claim 21. More particularly, claim 1 includes the features of "an output device in communication with the pad, the output device operatively adapted to indicate continuous transmuralility of the ablated tissue based on the sensed temperature" and also "wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." As discussed in detail above, these features are not shown or made obvious in Stern.

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Nagai is cited because it “discloses that it is known to provide a combination suction and temperature sensing element to hold a working surface in contact with the device for monitoring temperature” as set forth in the Office Action on page 4. Nagai relates to a system for attracting a work piece under vacuum, and gives an example of the work piece as a cathode-ray tube with a fluorescent screen. (Nagai, column 1, lines 8-9 and 22-23). Nagai does not provide the features missing from Stern with respect to claim 1, and it does not recognize or suggest a solution to the problems facing Applicants.

Because the amended features are missing from both Stern and Nagai separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claim 1 and also claims 2-4, 6-9, 12, 16, and 19, by virtue of their dependency, are patentably distinguishable and allowable over the combination of Stern in view of Nagai.

**Claims 5, 17 and 18**

Claims 5, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. US Patent No. 5,443,463 and Nagai et al. US Patent No. 5,172,949 as applied to claims 1 and 4 above, and further in view of Chinn US Patent No. 5,647,868. Claims 5, 17, and 18 depend from independent claim 1, which has been shown to be patentable over the combination of Stern in view of Nagai.

Chinn is cited because it “teaches that it is known to provide a display that includes a visual representation of the device to show sensed and performance output parameters during a surgical procedure” as set forth in the Office Action of page 5. Chinn does not teach or make obvious the features of “an output device in communication with the pad, the output device operatively adapted to indicate continuous transmural of the ablated tissue based on the sensed temperature” and also “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.” As discussed above, these features are neither shown nor made obvious in either Stern or Nagai.

Because the amended features are missing from Stern, Nagai, and Chinn separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit

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that claims 5, 17, and 18 are patentably distinguishable and allowable over the combination of Stern in view of Nagai as applied to claim 1 and further in view of Chinn.

**Claims 10 and 11**

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. US Patent No. 5,443,463 and Nagai et al. US Patent No. 5,172,949 as applied to claim 1 above, and further in view of Hoffman US Patent No. 4,682,605. Claims 10 and 11 depend from independent claim 1, which has been shown to be patentable over the combination of Stern in view of Nagai.

Hoffman is cited because it disclose “that it is old and well known to use temperature sensing devices such as liquid crystals and temperature sensing chemicals to provide detailed temperature mapping of tissue” as set forth in the Office Action at page 5. Hoffman does not teach or make obvious the features of “an output device in communication with the pad, the output device operatively adapted to indicate continuous transmural of the ablated tissue based on the sensed temperature” and also “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.” As discussed above, these features are neither shown nor made obvious in either Stern or Nagai.

Because the amended features are missing from Stern, Nagai, and Hoffman separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 10 and 11 are patentably distinguishable and allowable over the combination of Stern in view of Nagai as applied to claim 1 and further in view of Hoffman.

**Claims 23, 24 and 26-28**

Claims 23, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. US Patent No. 5,443,463 in view of the teachings of Chinn US Patent No. 5,647,868. Claims 23, 24 and 26-28 depend from independent claim 21, which is discussed in detail above with respect to Stern.

Chinn is cited because it “teaches that it is known to provide a display that includes a visual representation of the device to show sensed and performance output parameters during a

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surgical procedure” as set forth in the Office Action of page 6. Chinn does not teach or make obvious the features of “an output device in communication with the pad, the output device operatively adapted to indicate continuous transmurality of the ablated tissue based on the sensed temperature” and also “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue” as set forth in the independent claim. As discussed above, these features are neither shown nor made obvious in Stern. Chinn further does not teach or recognize the particular problems with thermal ablation and the need to form continuous lesions as Chinn deals with a cooling system.

Because the amended features are missing from both Stern and Chinn separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 22, 24, and 26-28 are patentably distinguishable and allowable over the combination of Stern in view of Nagai as applied to claim 1 and further in view of Chinn.

**Allowable Subject Matter**

The Examiner objected to claims 13-15 for being dependent upon rejected base claim 1, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Claims 13-15 are amended to be new independent claims that correspond with the limitations of the claims 13-15 and their base claim 1. Applicants respectfully submit that independent claims 13-15 are in patentable form.

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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-29 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-29 are respectfully requested.

Applicants hereby authorize the Commissioner for Patents to charge Deposit Account No. 50-0471 in the amount of \$460 to cover the fees as set forth under 37 C.F.R. 1.16(h)(i).

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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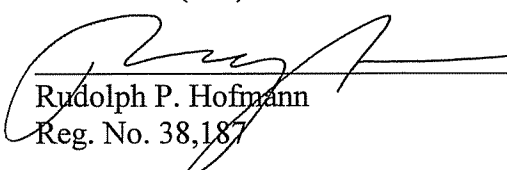
Respectfully submitted,

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By their attorneys,

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